Application No.:

10/509,498

Filing Date:

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REMARKS

Claim 1 has been amended. Support for the amendment is found in [0031] and [0036] of the published application (corresponding to page 6, first full paragraph & last paragraph of the present specification) and the Examples. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 102(b)

Claims 1-6 and 8-12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dalemans, et al. (WO 99/30733) (Dalemans).

Dalemans does not anticipate the claimed invention

The Examiner concedes that the claimed composition was produced by a different process than Dalemans but maintains that the end product taught by Dalemans is identical to Applicants' claimed product (Office Action, item 6, pages 4-7).

Claim 1 has been amended to: "...(c) one adjuvant, which is a mineral-based, negatively charged adjuvant...". Dalemans do not teach this limitation.

In the Office Action (page 7, lines 1-2), the Examiner states that Dalemans teach formulations combining protein antigen and adjuvant, referring to Dalemans at page 11, lines 3-8, which is reproduced below:

In a preferred embodiment of the invention the protein antigen is adsorbed to alum, and the alum particles are then coated with a bio-degradeable [sic] polymer such as poly (capro-lactone) or poly (lactide-co-glycolide). Unlike published methods for encapsulating protein antigen, such formulations provide a hermetic layer of polymer around the antigen, preventing antigen liberation for a period of time ranging from a day to several weeks.

This section corresponds to the teaching of Examples 8 and 9. These examples, however, describe slow-release vaccines in which the mineral-based adjuvant is *positively* charged and in which polycaprolactone is added as an additional adjuvant. Accordingly, Dalemans do not teach adding a *single adjuvant* which is a mineral-based and *negatively charged* as now claimed.

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Regarding the listing of adjuvants on page 9 of Dalemans, referred to in the Office Action at page 7, last two lines, again, Dalemans teaches the use of the mineral-based adjuvant in combination with a lipid based adjuvant. Relevant sections are reproduced below (emphasis added).

Adjuvants

The polynucleotides, polypeptides and polynucleotide + polypeptide mixture (complex) of the present invention, when adjuvanted, are preferably adjuvanted in the vaccine formulation of the invention. Vaccine preparation is generally described in New Trends and Developments in Vaccines, Voller et al. (eds.), University Park Press, Baltimore, Maryland, 1978. Fullerton describes *encapsulation within liposomes*, US Patent 4,235,877. Suitable adjuvants include an aluminum salt ...

Suitable adjuvant systems include, for example, a combination of monophosphoryl lipid A, preferably 3-de-O-acylated monophosphoryl lipid A (3D-MPL) together with an aluminum salt...

It is well settled that in order to have anticipation, the prior art reference "must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged as in the claim" (NetMoneyin, Inc. v. Verisign, Inc, No. 2007-1565, page 15, citing Connell v. Sears, Roebuck & Co. 722 F. 2d 1542, 1548 (Fed. Cir. 1983) (copy attached).

The rationale of using a coating such as poly-caprolactone or poly-lactide-co-glycolide to coat already adsorbed complexes of protein and "alum" is to provide a layer that delays release of adsorbed protein after exposure to interstitial fluid after injection. The immune system is not exposed to the antigen before the coating has dissolved. Dalemans is directed to a delaying principle that is not a part of the presently claimed invention. Dalemans teach that if the vaccine compositions are adjuvanted using a mineral-based adjuvant, it is in combination with a lipid or polymer component.

As stated in NetMoneyin, Inc. v. Verisign, Inc., "an anticipatory reference [need] show all of the limitations of the claims arranged or combined in the same way as recited in the claims" (ibid, pages 15-16). Dalemans generally teaches mineral-based adjuvants including aluminum phosphate which is negatively charged, but only in the context of combining the mineral-based adjuvant with a lipid or polymer. Accordingly Dalemans does not teach "one adjuvant, which is a mineral-based, negatively charged adjuvant" (claim 1 as amended). The disclosure of

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Dalemans is directed to a different technical problem than Applicants and does not teach "all of the limitations of the claims arranged or combined in the same way as recited in the claims" (ibid). Accordingly, the present claims are not anticipated by the teaching of Dalemans.

The claimed invention is patentable over Dalemans

Furthermore, the claims are not obvious over Dalemans in view of the unexpected results achieved by the claimed immunogenic compositions.

The present invention is based on the surprising finding that negatively-charged, mineral-based adjuvants (aluminum phosphate) further improve the enhancement of the immunogenicity of DNA vaccines by pre-incubation with a protein antigen.

As discussed in the present application (see paragraph 0039 of published U.S. application corresponding to pages 7-8, bridging paragraph of the present specification), mineral-adsorbed adjuvated protein vaccinations lead to a Th2 immunological response, at least in mouse models, characterized by a strong predominance of subtype IgG1 antibodies. The immunogenic compositions of the claimed invention provide a sufficient Th1 and a sufficient Th2 response within the same vaccine preparation which was unexpected in view of the art including Dalemans. By pre-incubating the negatively charged, mineral-based adjuvant with the protein antigen vaccine component prior to formulating with the polynucleotide vaccine component, both a Th1 and a Th2 response is obtained after administration of the vaccine. Furthermore, the antigen for which a Th2 response is desired can be predetermined by using that antigen as the protein antigen adsorbed onto the negatively charged mineral adjuvant, and, in the same vaccine preparation, the antigen for which a Th1 response is predetermined by providing that antigen as the DNA polynucleotide component.

This result is achieved by pre-incubation of a protein antigen with a negatively charged, mineral-based adjuvant. While Dalemans provides a listing of adjuvants on page 9, there is no teaching to direct one of ordinary skill in the art to select a negatively charged mineral-based adjuvant for preincubation with the protein component of the immunogenic composition.

Furthermore, Dalemans teaches that an adjuvant need not be used at all. In fact Examples 1-7 of Dalemans describe vaccine compositions without any adjuvant. Only Examples 8 & 9 describe the use of an adjuvant. These examples described preparation and use of slow-release

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vaccines in which a *positively charged* mineral-based adjuvant is premixed with a protein antigen (together with polycaprolactone) for a slow-release formulation and subsequently mixed with a DNA component. Accordingly, Examples 8 and 9, if anything, teach away from the claimed invention in teaching use of multiple adjuvants and a mineral-based adjuvant which is positive, not negative in charge.

Moreover, the synergistic effect of mixed DNA/ protein vaccines is absent in Dalemans.

In Example 3 of Dalemans, the DNA vaccination leads to a strong Th1 immunological response (characterized by a strong content of IgG2a), whereas the protein vaccination has a complete bias for the opposite, which is a Th2 response (characterized by a strong content of IgG1) The mixed DNA/protein vaccination however, also leads to a Th1 response, and not to a combined Th1/Th2 response (see page 18, lines 5-9 of Dalemans). These findings are further substantiated by the cytokine profile in Example 4 (see page 20, lines 23-28 of Dalemans) and the CTL induction in Example 5 (see page 22, lines 4-6 of Dalemans). Thus, a combination of DNA vaccine and a protein antigen leads to a Th1 response.

Example 7 of Dalemans describes the enhancement of the immunological response due to a time-shift in the antigen presentation by the DNA component and the protein component of the vaccine. The DNA component of the vaccine is administered as a prior vaccination to the protein component, which is administered in a subsequent vaccination. In this respect, Figure 5 (page 23, lines 23-26 of Dalemans) and Figure 6 (page 23, lines 28-30 of Dalemans) show an increased immunological response, characterized by an overall increased IgG titer, which is still predominated by IgG2a (thus Th1). Thus, Example 7 relates to two separate vaccinations: a DNA vaccination and a protein vaccination. No adjuvants were added. Also here, the DNA vaccination prior to the vaccination with a protein antigen leads to a Th1 response.

Examples 8 and 9 describe the preparation and use of delayed-release formulations, in order to allow simultaneous administration of both DNA and the corresponding protein antigen (see page 24, lines 27-28 of Dalemans). For this purpose, the protein antigen is premixed with a *positively* charged aluminum hydroxide *supplemented with a second adjuvant*, polycaprolactone (see page 24, lines 5-7 of Dalemans), for the specific purpose of creating a slow-release protein antigen component (see page 24, lines 16-19 of Dalemans). Subsequently the DNA component was added, prior to immunization. It is alleged that this form of immunization leads to an

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increased overall immunological response, comparable to Example 7, i.e., a Th1 response. The sole purpose for premixing both adjuvants with the protein antigen is to be able to create a slow-release formulation of the protein antigen due to the presence of the second adjuvant, polycaprolactone, but *not* to differentiate the response (i.e., Th1 and Th1).

As such, Dalemans teaches that positively charged mineral-based adjuvants can be used in combination with polycaprolactone to create slow-release vaccines when pre-incubated with a protein antigen prior to adding a DNA component to formulate a vaccine. Such vaccine, however, do not exhibit a synergistic effect of the protein and DNA components. That is, not differentiation of an immune response is accomplished.

This is in stark contrast to the present invention, which relates to combination vaccines with a pre-determined and differentiated immunological response, i.e., both a Th1 and Th2 response are elicited, directed against the antigen encoded by the DNA component or the protein component, respectively.

Moreover, the use of such negatively charged mineral-based adjuvants can be used to prime not only an enhanced, but also a differentiated immunological response, i.e., the copriming of multispecific, humoral and cellular immune responses. This can be appreciated from Figure 1, and paragraph 0041 of the U.S. published application (present specification, page 8, last paragraph) which shows that Th1, Th2 and mixed Th1/Th2 immunological responses are supported by the vaccines prepared according to the method provided in the present invention.

Furthermore, as stated in paragraph 0035 of the published U.S. application (corresponding to present specification at page 6, lines 21-25), the vaccine composition in which the adjuvant has been pre-incubated with the protein antigen has a different appearance compared to the original vaccine formulations. Accordingly, the vaccine formulations according to the claimed invention are structurally different from vaccine formulations in which the adjuvant has **not** been pre-incubated with the protein antigen as in the prior art.

Criticality of the use of a negatively charged adjuvant is shown by the graph on page 6 of the published U.S. application (present specification, page 12, lines 20-30). As stated (last paragraph of page 12 of the present specification), the protein antigen was readily detected in S/N of mixtures of antigen with aluminum phosphate but *not* after incubation with aluminum hydroxide. The graph demonstrates the adsorption of an acidic IEP protein antigen to aluminum

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hydroxide but not to aluminum phosphate. Accordingly, the aluminum hydroxide adjuvant taught by Dalemans in Examples 8 and 9 is **not** equivalent to the negatively charged adjuvant, such as aluminum phosphate and aluminum hydroxyphosphate (see present specification at page 9, first paragraph).

The present claims are directed to a single vaccine composed of very different types of vaccine constructs that prime a diverse spectrum of immune responses. As such, the pre-mixing of the protein antigen with a negatively charged mineral-based adjuvant prior to formulating a vaccine together with a DNA component does not result in the same vaccine as disclosed in the prior art, because the properties as well as physical structure of the vaccines descried in the present invention differ from the properties and physical structure of the prior art vaccines.

A comparison of the examples provided in Dalemans with the examples provided in the present application demonstrate that the vaccine compositions of Dalemans and the present application are indeed different, both in structure and in effect due to the order of mixing of the components and the specific use of a single negatively charged mineral-based adjuvant.

Accordingly, the claimed invention is not taught by Dalemans.

- Dalemans does not teach a single negatively charged mineral-based adjuvant.
 Dalemans teaches mineral-based adjuvants in combination with a second adjuvant. Furthermore, Dalemans does not exemplify use of negatively charged adjuvants.
 Dalemans does not distinguish between negatively- and positively-charged adjuvants.
- Dalemans teach a vaccine composition that is structurally different from the vaccine compositions of the prior art as indicated by its different physical appearance.

The claimed invention is not inherently anticipated

Furthermore, these features are not inherently present in Dalemans. the requirements for "inherent" anticipation have been well-established by the Court of Appeals for the Federal Circuit, and are summarized in M.P.E.P. § 2112.IV, as follows:

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"The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is <u>not sufficient</u> to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is <u>necessarily</u> present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may <u>not</u> be established by <u>probabilities</u> or <u>possibilities</u>. The mere fact that a certain thing <u>may</u> result from a given set of circumstances is <u>not sufficient</u>.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ..." [emphasis added]

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Thus, to establish inherent disclosure of a claim element, it must be shown that the prior art reference <u>necessarily</u> discloses that element; it is not sufficient to show that the reference possibly or even probably discloses the element in question.

In the present case, it is clear that Dalemans does not inherently teach the vaccine compositions of the present claims as evidenced by their different properties discussed above.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

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any alterations or characterizations are being made to facilitate expeditious prosecution of this

application. Applicant reserves the right to pursue at a later date any previously pending or other

broader or narrower claims that capture any subject matter supported by the present disclosure,

including subject matter found to be specifically disclaimed herein or by any prior prosecution.

Accordingly, reviewers of this or any parent, child or related prosecution history shall not

reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter

supported by the present application. Any amendments and observations made herein are made

solely for the purposes of the prosecution of this US patent application and without prejudice to

the Application to other jurisdictions.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is

respectfully submitted that the present application is in condition for allowance. Should the

Examiner have any remaining concerns which might prevent the prompt allowance of the

application, the Examiner is respectfully invited to contact the undersigned at the telephone

number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or

credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 30, 2009

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-12-

United States Court of Appeals for the Federal Circuit

2007-1565

NET MONEYIN, INC.,

Plaintiff-Appellant,

٧.

VERISIGN, INC.,

Defendant-Appellee,

and

EPROCESSING NETWORK,

Defendant-Appellee,

and .

BANKCARD CENTER, INC., WEBTRANZ, VALIDPAY.COM, INC., ORDERBUTTON.NET, INC., SECUREPAY.COM, INC., GLOBILL.COM LLC, IB HOLDING COMPANY, LTD., E-COMMERCE EXCHANGE LLC, ITRANSACT.COM INFOSPACE, INC., CITIBANK, and ELECTRONIC PAYMENT PROCESSING, INC.,

Defendants.

<u>William A. Birdwell</u>, Davis Wright Tremaine LLP, of Portland, Oregon, argued for plaintiff-appellant. With him on the brief was <u>Timothy R. Volpert</u>. Of counsel on the brief was <u>Allen Field</u>, Law Office of Allen Field, of Portland, Oregon.

J. Michael Jakes, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, argued for defendants-appellees. With him on the brief for Verisign, Inc., were Thomas W. Winland and Scott A. Herbst, of Palo Alto, California.

<u>Corby R. Vowell</u>, Goldstein, Faucett & Prebeg, LLP, of Houston, Texas, for defendant-appellee EProcessing Network.

Appealed from: United States District Court for the District of Arizona

Judge Raner C. Collins

United States Court of Appeals for the Federal Circuit

2007-1565

NET MONEYIN, INC.,

Plaintiff-Appellant,

٧.

VERISIGN, INC.,

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and

EPROCESSING NETWORK,

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and

BANKCARD CENTER, INC., WEBTRANZ, VALIDPAY.COM, INC., ORDERBUTTON.NET, INC., SECUREPAY.COM, INC., GLOBILL.COM LLC, IB HOLDING COMPANY, LTD., E-COMMERCE EXCHANGE LLC, ITRANSACT.COM INFOSPACE, INC., CITIBANK, and ELECTRONIC PAYMENT PROCESSING, INC.,

Defendants.

Appeal from the United States District Court for the District of Arizona in case no. 01-CV-441, Judge Raner C. Collins.

DECIDED: October 20, 2008

Before LINN, CLEVENGER, and MOORE, Circuit Judges.

LINN, Circuit Judge.

Net MoneyIN, Inc. ("NMI") appeals from a final judgment of the United States District Court for the District of Arizona, which held the asserted claims of U.S. Patents No. 5,822,737 ("the '737 patent") and No. 5,963,917 ("the '917 patent") invalid. NMI

also appeals from the district court's denial of its motion for leave to amend its complaint to assert a claim for inducement of infringement. Because the district court correctly found claims 1, 13, and 14 of the '737 patent and claim 1 of the '917 patent, which contain limitations in means-plus-function format, invalid under 35 U.S.C. § 112 ¶ 2 as lacking corresponding structure, we affirm that portion of the judgment. Because the district court did not abuse its discretion in denying NMI's motion to amend, we also affirm that ruling. Because the district court applied an incorrect standard of law in finding claim 23 of the '737 patent invalid as anticipated under 35 U.S.C. § 102(a), however, we reverse the grant of summary judgment of anticipation. Thus, we affirm-in-part, reverse-in-part, and remand for proceedings consistent with this opinion.

I. BACKGROUND

This case involves systems for processing credit card transactions over the Internet and for addressing security concerns not present in direct retail transactions. In the early days of Internet commerce, merchants recognized that one key to the success of Internet sales would be the ability to provide customers with assurances of security in the processing of financial transactions over the Internet using credit cards, bank accounts, and other means of electronic payment. Responding to that need, the industry investigated encryption techniques and architectures to protect sensitive data. One such effort is reflected in a 1995 working document entitled "Internet Keyed Payments Protocol ("the iKP reference"), published by the Internet Engineering Task Force and IBM. That document sets forth standards on "how payments may be accomplished efficiently, reliably[,] and securely." J.A. at 1375. The iKP reference explains that its goal was "to enable Internet-based secure electronic payments while

utilizing the existing financial infrastructure for payment authorization and clearance. The intent is to avoid completely, or at least minimize, changes to the existing financial infrastructure outside the Internet." <u>Id.</u> To that end, the iKP reference suggests two standard models, or protocols.¹

In the first protocol, (1) the customer selects one or more items to purchase from the merchant's website; (2) the customer sends credit card information to the merchant; (3) the merchant sends the credit card information and amount of the purchase to the merchant's bank; (4) the merchant's bank seeks authorization for the purchase from the issuing bank over the existing banking network; and (5) the merchant's bank notifies the merchant (but not the customer) of transaction approval. See id. at 1381 (flow diagram); Appellant's Br. at 7.

In the second protocol, (1) the customer selects one or more items to purchase on the merchant's website; (2) the customer sends an authorization request, along with its credit card information and the amount of the purchase, to the merchant's bank; (3) the merchant's bank seeks authorization from the issuing bank over the existing banking network; (4) the merchant's bank notifies the customer of transaction approval; and (5) the customer sends the authorization response to the merchant. See J.A. at 1342, 1394; Appellant's Br. at 8-9.

Unsatisfied with the early approaches taken by others, Mark Ogram, an inventor and patent attorney, set out to create a new payment model to remedy what he

As illustrated by our colloquy with counsel at oral argument, it is not clear whether the payment models disclosed in the iKP reference are mutually exclusive. Viewing the facts in the light most favorable to NMI, however, as we must do at this stage in the proceedings, the reference is properly construed to show two mutually exclusive payment models.

perceived as two deficiencies in the prior art protocols: "the fact that the customer had to send confidential information over the Internet to an unknown merchant; and the fact that credit card issuers imposed onerous financial requirements on merchants." Appellant's Br. at 10. Ogram's idea was to add a fifth entity, a "payment processing" or "financial processing" entity, to supplement the conventional model with four entities: the customer, merchant, merchant's bank, and issuing bank. According to Ogram, the new financial processing entity would: "(1) receive credit card account information and an amount to be charged from the customer when the customer placed the order; (2) seek authorization from the card issuer over the existing banking network; and (3) notify both the customer and the merchant of authorization." Id.

On February 5, 1996, Ogram filed a patent application directed to a payment model utilizing a financial processing entity. He formed NMI shortly thereafter to implement the model as a business for processing credit card transactions over the Internet. Ogram's patent application resulted in the '737 and '917 patents, both of which are assigned to NMI. Claim 1 of the '737 patent is illustrative of the invention claimed:

- 1. A financial transaction system comprising:
 - a) a first bank computer containing financial data therein, said financial data including customer account numbers and available credit data, said first bank computer including means for generating an authorization indicia in response to queries containing a customer account number and amount;
 - b) a merchant computer containing promotional data;
 - c) a customer computer being linked with said merchant computer and receiving said promotional data; and,
 - d) a financial processing computer remote from said merchant computer and having means for:
 - 1) receiving customer account data and amount data from said customer computer,
 - 2) querying said first bank computer with said customer account data and said amount data,

- 3) receiving an authorization indicia from said first bank computer,
- 4) communicating a self-generated transaction indicia to said customer computer, and,
- 5) communicating the self-generated transaction indicia to said merchant computer.

According to their abstracts, the '737 and '917 patents relate to "[a]n automated payment system particularly suited for purchases over a distributed computer network such as the Internet."

In 2001, NMI filed suit for infringement of the '737 and '917 patents against a number of parties alleged to compete in the Internet credit card processing field, including VeriSign, Inc. and eProcessing Network (collectively, "VeriSign"). Following a claim construction hearing, the district court construed a number of terms in dispute. Net MoneyIN, Inc. v. VeriSign, Inc., No. 01-CV-441 (D. Ariz. Oct. 18, 2005) ("Claim Construction Decision"). As part of its construction of the claim terms, the district court invalidated claims 1, 13, and 14 of the '737 patent and claim 1 of the '917 patent, which contain limitations in means-plus-function format, as lacking corresponding structure and thus indefinite under 35 U.S.C. § 112 ¶ 2.

Following construction of the claims, the district court entertained two motions for summary judgment that are relevant to this appeal. First, VeriSign moved for summary judgment that it did not induce infringement of NMI's patents. In response to that motion, NMI moved for leave to amend its complaint to add a claim for inducement of infringement. The district court granted VeriSign's motion for summary judgment and denied NMI's motion for leave to amend. Net MoneyIN, Inc. v. VeriSign, Inc., No. 01-CV-441 (D. Ariz. June 8, 2006) ("Amendment Decision"). Second, VeriSign moved for summary judgment of invalidity, arguing that the iKP reference anticipated claim 23 of

the '737 patent under 35 U.S.C. § 102(a). The district court granted VeriSign's motion.

Net MoneyIN, Inc. v. VeriSign, Inc., No. 01-CV-441 (D. Ariz. July 13, 2007) ("Summary Judgment Decision"). The district court then entered final judgment in favor of VeriSign.

NMI timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

Claim construction is a question of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), over which we exercise plenary review. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Indefiniteness under 35 U.S.C. § 112 ¶ 2 is also a question of law subject to plenary review. SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1338 (Fed. Cir. 2005).

We review a grant of summary judgment de novo, reapplying the standard that the district court employed. Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1301 (Fed. Cir. 1999). Drawing all reasonable inferences in favor of the nonmovant, "[s]ummary judgment is appropriate only when 'there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Id. (quoting Fed. R. Civ. P. 56(c)).

The denial of a motion to amend is a procedural question not unique to patent law and thus is reviewed under the law of the regional circuit. <u>Kalman v. Berlyn Corp.</u>, 914 F.2d 1473, 1480 (Fed. Cir. 1990). In the Ninth Circuit, the denial of a motion to amend is reviewed for abuse of discretion. <u>Chappel v. Lab. Corp. of Am.</u>, 232 F.3d 719, 725 (9th Cir. 2000).

B. Analysis

1. Indefiniteness

The district court concluded that claims 1, 13, and 14 of the '737 patent and claim 1 of the '917 patent were indefinite under 35 U.S.C. § 112 \P 2, and thus invalid. Because each of these patents raises different issues, we address them separately.

a. the '737 patent

Claim 1 of the '737 patent recites a financial transaction system comprising, among other things, "a first bank computer containing financial data therein, said financial data including customer account numbers and available credit data, said first bank computer including means for generating an authorization indicia in response to queries containing a customer account number and amount" (emphasis added). The district court construed the generating means element in claim 1 as a means-plusfunction element. The parties agreed that the function of the claimed means was "generating an authorization indicia in response to queries containing a customer account number and amount." The district court found, however, that the specification failed to disclose any corresponding structure to perform the claimed function. Accordingly, it deemed the claim invalid under 35 U.S.C. § 112 ¶ 2.

NMI argues that the generating means element is not a means-plus-function element under 35 U.S.C. § 112 ¶ 6 "because the claim itself discloses sufficient structure which performs the function of 'generating an authorization indicia in response to queries containing a customer account number and amount." Appellant's Br. at 21

NMI does not make arguments with respect to claims 13 or 14, which contain language similar to that in claim 1. We view this as a concession that these claims rise or fall with claim 1.

(emphasis omitted). Alternatively, NMI contends that if the generating means claim element is properly construed as a means-plus-function element, then the specification recites sufficient structure to make the claim definite. VeriSign counters that the district court correctly concluded both that the claim does not recite sufficient structure to rebut the means-plus-function presumption and that the specification contains insufficient structure to perform the claimed function.

Section 112, paragraph 6, of title 35 provides that:

An element of a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

A claim element that contains the word "means" and recites a function is presumed to be drafted in means-plus-function format under 35 U.S.C. § 112 ¶ 6. Envirco Corp. v. Clestra Cleanroom, Inc., 209 F.3d 1360, 1364 (Fed. Cir. 2000). The presumption is rebutted, however, "if the claim itself recites sufficient structure to perform the claimed function." Id.; see also Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1427-28 (Fed. Cir. 1997) ("[W]here a claim recites a function, but then goes on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function, the claim is not in means-plus-function format.").

We first address NMI's contention that the presumption triggered by the presence of the word "means" in claim 1 is rebutted by the recitation of sufficient structure for performing entirely the recited function of "generating an authorization indicia." NMI contends that the language, "first bank computer containing financial data therein, said financial data including customer account numbers and available credit data, said first bank computer . . . generating an authorization indicia in response to queries containing

a customer account number and amount," is sufficient structure to rebut the means-plus-function presumption. NMI argues that an ordinary artisan would understand the "bank computer" "to be a commonly known structure for generating authorization indicia in response to queries containing a custom account number and amount." Appellant's Br. at 21, 22. VeriSign responds that the claim does not recite sufficient structure to rebut the presumption "because of the wide variety of types and classes of computers in existence, each being configurable in a variety of different ways using many different programming languages." Appellees' Br. at 28 (internal quotation marks and citations omitted).

We agree with VeriSign that the recitation in claim 1 of the "bank computer" is not sufficient to rebut the means-plus-function presumption. The bank computer is not linked in the claim as the "means" for generating an authorization indicia. Rather, the bank computer is recited as "including" those means. NMI's argument that the first bank computer constitutes sufficient structure would require the first bank computer to include a first bank computer, which is both redundant and illogical. Because the claimed generating means is a subset of the bank computer, there must be a recitation of structure that is a component of the bank computer to rebut the presumption. The claim contains no such recitation. As a result, the district court correctly concluded that the presumption of means-plus-function treatment had not been overcome.

Having concluded that the generating means recited in claim 1 is drafted in means-plus-function format, we turn to whether the specification includes a disclosure of structure sufficient to accomplish the recited function. NMI argues that "the specification does disclose a 'bank computer' and this Court's precedents do not require

a description of the 'internal structure' of the 'bank computer." Appellant's Br. at 27 (emphasis omitted); see also id. at 31 ("Here, claim 1(a) itself states that the 'bank computer' contains 'financial data' including 'customer account numbers and available credit data.' A person skilled in the art would know that such a computer would be programmed to compare account data and amount data to those data structures and generate an authorization indicia if credit were available."). VeriSign counters that the district court correctly determined that the '737 patent specification fails to disclose the "structure corresponding to what, in the claimed first bank computer, performs the claimed generating function." Appellees' Br. at 51 (internal quotation marks omitted).

A patent applicant who employs means-plus-function language "must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195 (Fed. Cir. 1994) (en banc). To avoid purely functional claiming in cases involving computer-implemented inventions, we have "consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor." Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech., 521 F.3d 1328, 1333 (Fed. Cir. 2008). "Because general purpose computers can be programmed to perform very different tasks in very different ways, simply disclosing a computer as the structure designated to perform a particular function does not limit the scope of the claim to 'the corresponding structure, material, or acts' that perform the function, as required by section 112 paragraph 6." Id. "Thus, in a means-plus-function claim 'in which the

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disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." <u>Id.</u> (quoting <u>WMS Gaming, Inc. v. Int'l Game Tech.</u>, 184 F.3d 1339, 1349 (Fed. Cir. 1999)). Consequently, a means-plus-function claim element for which the only disclosed structure is a general purpose computer is invalid if the specification fails to disclose an algorithm for performing the claimed function. <u>See id.</u> at 1337-38.

There is no dispute in this case that the specification fails to disclose an algorithm by which a general purpose bank computer "generat[es] an authorization indicia." As a result, the district court correctly concluded that claims 1, 13, and 14 are indefinite under 35 U.S.C. § 112 ¶ 2. We therefore affirm that part of the judgment.

b. the '917 patent

Claim 1 of the '917 patent recites a financial transaction system comprising, among other things, "a financial processing computer . . . having automatic means responsive to [the] order for . . . receiving customer account data and amount data from [the] customer computer and [the] merchant computer." The parties do not dispute the district court's construction of this claim element as a means-plus-function element. The parties do dispute, however, the nature of the function. The district court construed the function as "the financial processing computer receives both the customer account data and amount data from both the customer computer and the merchant computer."

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At oral argument, counsel for NMI conceded that "[t]here is nothing in the written description that expressly states what is going on inside that bank computer." Oral Arg. at 20:10-20:15, available at http://oralarguments.cafc.uscourts.gov/mp3/2007-1565.mp3.

Claim Construction Decision at 11. NMI argues that the district court's construction of the function is erroneous. According to NMI, the ordinary meaning of the claim language requires that the function be construed more broadly: "[I]n response to an order, the financial processing computer: (1) receives customer account data from the customer computer, the merchant computer, or both; and (2) it also receives amount data from the customer computer, the merchant computer, or both." Appellant's Br. at 46-47. VeriSign counters that the district court correctly construed the function according to the ordinary meaning of the claim language.

The language of the function at issue was construed by the district court as specifying that both the amount data and the account data must come from both the customer computer and the merchant computer. That construction comports with and is fully supported by the language of the claim itself. NMI argues that the function is subject to a different construction, which would permit the amount data and the account data to come from the merchant computer, the customer computer, or both. The problem with NMI's proffered construction, however, is that it is different from, and broader in scope than, the construction it asserted in the district court. See J.A. at 1046 (arguing to the district court that "the meaning of this element is: "the financial processing computer receives the customer account data from the customer computer and the amount data from the merchant computer via the customer computer"). This is not merely a new argument in support of a previously presented construction, but instead is a new and more expansive construction, which may not properly be asserted on appeal. See Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1347 (Fed. Cir. 2001). Because NMI's new construction is not proper on appeal, and

because we see no basis on which to overturn the district court's construction, that construction is affirmed.

NMI concedes that under the district court's construction, no structure is disclosed in the specification to perform the claimed function. Appellant's Br. at 46. As a result, the claim is indefinite under 35 U.S.C. § 112 ¶ 2. See Donaldson, 16 F.3d at 1195. Consequently, we affirm the district court's determination that claim 1 of the '917 patent is invalid.

2. Anticipation

Claim 23 of the '737 patent recites an Internet payment system comprising five "links":

- a) a first link between a customer computer and a vending computer for communicating promotional information from said vending computer to said customer computer;
- a second link, initiated by said customer computer, between said customer computer and a payment processing computer, remote from said vending computer, for communicating credit card information and amount from said customer computer to said payment processing computer;
- c) a third link, initiated by said payment processing computer with a credit card server computer for communicating said credit card information and said amount from said payment processing computer to said credit card server computer, and for communicating, in response, an authorization indicia from said credit card server computer to said payment processing computer; []
- d) a fourth link between said payment processing computer and said customer computer for communicating a transactional indicia[;]
- [e)] a fifth link between the payment processing computer and said vending computer for communicating said transactional indicia.

The district court, after finding all five of these links in the iKP reference, albeit in two separate disclosed examples, concluded that claim 23 was anticipated under 35 U.S.C. § 102(a) and therefore invalid. Specifically, the district court concluded:

All of the limitations of claim 23 can be found within the iKP reference. A simple combination would produce the system described in claim 23 of the '737 patent. That no specific example within iKP contains all five links does not preclude a finding of anticipation.

Summary Judgment Decision at 3. NMI contends that the district court's combination of two disclosed examples in order to find all elements of the claim was erroneous. VeriSign responds that the district court did not improperly rearrange the links in the iKP reference, but rather "merely relied on various express teachings from a single document that together completely disclose the five claimed links." Appellees' Br. at 61. Under VeriSign's theory, this was sufficient to establish anticipation, because all that is required is "that the four corners of a single, prior art document describe every element of the claimed invention." Id. at 61-62 (quoting Xerox Corp. v. 3Com Corp., 458 F.3d 1310, 1322 (Fed. Cir. 2006)). We disagree with VeriSign, and take this opportunity to clarify what a reference must show in order to anticipate a claimed invention.

Section 102(a) provides that an issued patent is invalid if "the invention [therein] was . . . described in a printed publication . . . before the invention thereof by the applicant." Section 102 embodies the concept of novelty—if a device or process has been previously invented (and disclosed to the public), then it is not new, and therefore the claimed invention is "anticipated" by the prior invention. As we have stated numerous times (language on which VeriSign relies), in order to demonstrate anticipation, the proponent must show "that the four corners of a single, prior art document describe every element of the claimed invention." Xerox, 458 F.3d at 1322 (quoting Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed.

Because it is on this ground that we decide this issue, we do not reach NMI's alternative grounds for reversing the district court's anticipation conclusion.

Cir. 2000)). This statement embodies the requirement in section 102 that the anticipating invention be "described in a printed publication," and is, of course, unimpeachable. But it does not tell the whole story. Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged as in the claim." Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983).⁵

The meaning of the expression "arranged as in the claim" is readily understood in relation to claims drawn to things such as ingredients mixed in some claimed order. In such instances, a reference that discloses all of the claimed ingredients, but not in the order claimed, would not anticipate, because the reference would be missing any disclosure of the limitations of the claimed invention "arranged as in the claim." But the "arranged as in the claim" requirement is not limited to such a narrow set of "order of limitations" claims. Rather, our precedent informs that the "arranged as in the claim" requirement applies to all claims and refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as

VeriSign points to language in <u>Glaxo Group Ltd. v. Apotex, Inc.</u>, 376 F.3d 1339, 1348 (Fed. Cir. 2004), on which the district court relied, which states: "Apotex is of course correct that anticipation requires that all limitations of the claimed invention are described in a single reference, rather than a single example in the reference." This does not say what VeriSign wishes it did, nor could it. This language, when read in context, stands for the unremarkable proposition that courts are not constrained to proceed example-by-example when reviewing an allegedly anticipating prior art reference. Rather, the court must, while looking at the reference as a whole, conclude whether or not that reference discloses all elements of the claimed invention arranged as in the claim.

recited in the claims, not merely in a particular order. The test is thus more accurately understood to mean "arranged or combined in the same way as in the claim."

For example, in Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452 (Fed. Cir. 1984), we reviewed a district court's determination that a patent directed to a hydraulic scrap shearing machine was anticipated by a prior patent directed to a method for shearing spent nuclear fuel bundles. Because the district court had "treated the claims as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning," we reversed. Id. at 1459. Although the prior art reference could be said to contain all of the elements of the claimed invention, it did not anticipate under 35 U.S.C. § 102 because it "disclose[d] an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a different way to process different material differently." Id. at 1458. The reference thus was deficient because it did not disclose the elements of the claimed invention "arranged as in the claim" as required by 35 U.S.C. § 102. Id.

In Ecolochem, Inc. v. Southern California Edison Co., 227 F.3d 1361 (Fed. Cir. 2000), we reviewed a district court's decision that a prior art reference directed to "Saving Energy by Catalytic Reduction of Oxygen in Feedwater" anticipated a claim reciting the use of hydrazine with a mixed resin bed to deoxygenate water. In finding that the reference anticipated the claim, the district court considered a figure and accompanying text, which taught the use of hydrogen with a mixed bed to deoxygenate water, in conjunction with a separate passage discussing deoxygenating water with, among other things, hydrazine. <u>Id.</u> at 1369. We reversed. After determining that the

relevant figure and accompanying text described only the use of hydrogen to deoxygenate water, we concluded that the reference could not anticipate the claimed invention because there was no link between that figure and the general discussion of hydrazine as a deoxygenating agent. <u>Id.</u> In other words, we concluded that although the reference taught all elements of the claim, it did not contain a discussion suggesting or linking hydrazine with the mixed bed in the figure, and thus did not show the invention arranged as in the claim.

Recently, in <u>Finisar Corp. v. DirecTV Group, Inc.</u>, 523 F.3d 1323 (Fed. Cir. 2008), we reversed a district court's denial of a motion for judgment as a matter of law because the jury could not have reasonably concluded that the prior art reference relating to the Videotex architecture did not anticipate the claimed invention directed to systems and methods for scheduling transmission of database tiers on demand at varying repetition rates. Although the anticipation issue dealt largely with the interpretation of the prior art reference, <u>id.</u> at 1335-37, we reemphasized the importance of the requirement that the reference describe not only the elements of the claimed invention, but also that it describe those elements "arranged as in the claim":

To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. . . . But disclosure of each element is not quite enough—this court has long held that "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim."

Id. at 1334 (quoting Connell, 722 F.2d at 1548). In all of these cases, the prior art reference had to show the claimed invention arranged or combined in the same way as recited in the claim in order to anticipate. We thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the

claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Here, the iKP reference discloses two separate protocols for processing an Internet credit card transaction. Neither of these protocols contains all five links arranged or combined in the same way as claimed in the '737 patent. Thus, although the iKP reference might anticipate a claim directed to either of the two protocols disclosed, it cannot anticipate the system of claim 23. The district court was wrong to conclude otherwise.

The district court was also wrong to combine parts of the separate protocols shown in the iKP reference in concluding that claim 23 was anticipated. Granted, there may be only slight differences between the protocols disclosed in the iKP reference and the system of claim 23. But differences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation. See 35 U.S.C. § 103(a) ("A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." (emphasis added)); see also In re Arkley, 455 F.2d 586, 587 (CCPA 1972) ("[R]ejections under 35 U.S.C. § 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art." (emphasis and internal quotation marks omitted)). Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct

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teachings that the artisan might somehow combine to achieve the claimed invention. See Arkley, 455 F.2d at 587 ("[T]he [prior art] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.").

Because the parties do not contend that the iKP reference discloses all of the limitations recited in claim 1 arranged or combined in the same way as in the claim, and because it was error for the district court to find anticipation by combining different parts of the separate protocols in the iKP reference simply because they were found within the four corners of the document, we reverse the district court's grant of summary judgment of invalidity.

3. Motion to Amend

During the course of this litigation, NMI filed a Second Amended Complaint in which it clarified that it was asserting, among other things, a claim for inducement of infringement under 35 U.S.C. § 271(b). In a Third Amended Complaint filed in August 2003, however, NMI abandoned its claim for inducement of infringement, stating that it had "elected not to assert a cause of action for inducement." In answering NMI's Third Amended Complaint, although some of the defendants reasserted counterclaims for declaratory judgment of noninfringement by inducement, VeriSign did not. J.A. at 1251.

In May 2005, VeriSign moved for partial summary judgment on inducement of infringement. In response, NMI moved, pursuant to Federal Rule of Civil Procedure 15(b), for leave to file a Fourth Amended Complaint to add a claim for inducement of infringement. According to NMI, VeriSign had consented to litigate the issue by moving

for summary judgment on that basis. The district court granted VeriSign's motion for partial summary judgment and denied NMI's motion to amend.

NMI argues that the district court abused its discretion by denying the motion to amend. According to NMI, the district court had no discretion to deny amendment under Rule 15(b) because VeriSign consented to litigate the issue. VeriSign argues that, while it did seek partial summary judgment on the issue of inducement, it did so on the ground of waiver, not on the merits. Thus, according to VeriSign, it was within the district court's discretion to deny amendment.

A district court generally enjoys broad discretion when assessing the propriety of a motion to amend. See Chappel, 232 F.3d at 725. It does not enjoy such discretion, however, and amendment is mandatory, when an issue is tried with the express or implied consent of the parties. See Fed. R. Civ. P. 15(b) ("When an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings."); cf. Wallin v. Fuller, 476 F.2d 1204, 1210 (5th Cir. 1973) ("Amendment is thus not merely discretionary but mandatory in such a case.").

Thus, the first issue we must address is whether VeriSign consented, either expressly or impliedly, to litigate inducement. We agree with the district court that it did not. VeriSign's motion for partial summary judgment stated, in pertinent part,

NMI's failure to assert any claim of contributory infringement under Section 271(c) in its Third Amended Complaint, its express disavowal in that pleading of any claim of inducement under Section 271(b), its failure to disclose any indirect infringement theories or supporting evidence in its Supplemental Disclosure to VeriSign, and its failure to disclose any evidence that would establish indirect infringement, including its failure to identify any alleged direct infringer or any acts by VeriSign alleged to

constitute contributory infringement, compels entry of partial summary judgment in favor of VeriSign.

J.A. at 7330. This is not an attempt by VeriSign to litigate induced infringement on the merits. Given NMI's repeated amendment of its complaint, including its history of dropping inducement claims only to later add them, as well as VeriSign's understanding that NMI planned to resurrect the claim at trial, it is apparent that VeriSign's motion was made to foreclose NMI's ability to later raise inducement (again). Notably, this is precisely how the district court construed NMI's motion:

Plaintiff uses the argument that by filing [a] motion for summary judgment on this issue, the Defendants are consenting to its litigation. This is not the case. Defendants are merely attempting to formally discharge this theory as a claim (as has already been indicated by Plaintiffs counsel) so that the case can be focused on the theory of direct infringement.

Amendment Decision at 7. Thus, the district court was not without discretion to deny the requested amendment.

The question thus becomes whether the district court's denial of the motion was an abuse of that discretion. In denying the motion, the district court observed that NMI was requesting leave "to amend [its] Complaint for a fourth time in order to allege a claim (inducement of infringement) which [it] ha[s] expressly disavowed, twenty months after the deadline to amend pleadings and four months after the close of discovery." Id. at 6-7. It also observed that granting NMI's motion would result in "extreme delay," id. at 10, and severe prejudice to VeriSign, id. at 11. Under these circumstances, we cannot find that the district court's denial was an abuse of discretion. See Chappel, 232 F.3d at 725-26 ("A district court acts within its discretion to deny leave to amend when amendment would be futile, when it would cause undue prejudice to the defendant, or when it is sought in bad faith.").

III. CONCLUSION

For the foregoing reasons, we <u>AFFIRM-IN-PART</u>, <u>REVERSE-IN-PART</u>, and <u>REMAND</u> for proceedings consistent with this opinion.

COSTS

No costs.